Message

From: Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]
Sent: 11/4/2019 3:09:33 PM
To: Doherty, Michael [Doherty.Michael@epa.gov]
CC: Metzger, Michael [Metzger.Michael@epa.gov]; Niman, Aaron (niman.aaron@epa.gov) [niman.aaron@epa.gov]
Subject: FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

I agree. It certainly implies this without saying it.

I think I will write to Earl I., Calvin F. et al. on this and see what he says.

David.

From: Doherty, Michael <Doherty.Michael@epa.gov>
Sent: Monday, November 04, 2019 10:03 AM
To: Niman, Aaron <niman.aaron@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

This implies that EPA will be providing the aldicarb studies to CCPR. My understanding was that we would/could not do so. Has something changed?

If we are not going to provide the studies, then I think we need to communicate that to Ian et al. so we can stop this as an expected path forward.

My $0.02.

Mike

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Michael Doherty, Ph.D.
Office of Pesticide Programs
Health Effects Division
Risk Assessment Branch II
703-305-1031

From: Larry Hodges <larryhodges@meycorp.com>
Sent: Monday, November 4, 2019 9:58:35 AM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; MADSEN, Soren <madsens@who.int>
Cc: VERGER, Philippe <vergerp@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl <IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com>; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Mr. Reichstein and Mr. Madsen,

As previously explained, AgLogic Chemical (the current and only registrant of aldicarb) is committed to supporting the existing aldicarb MRLs but we do not have access to the aldicarb studies. These studies were submitted to the US EPA by Bayer CropScience and it is unlikely that the US EPA will be able to provide the aldicarb studies to the CCPR by December 1, 2019. As it is extremely important that aldicarb not be removed from the CCPR list of pesticides we

propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the US EPA to submit the studies to the CCPR.

Please respond to this email and let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Larry Hodges
Sent: Thursday, October 10, 2019 1:08 PM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; MADSEN, Soren <madsens@who.int>
Cc: VERGER, Philippe <vergerp@who.int>; YongZhen.Yang@fao.org; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl ; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>
Subject: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Mr. Reichstein and Mr. Madsen,

I am sending this email to advise you of the current status of the data submission for aldicarb (117) and to ask for guidance on the path forward. The attached two documents, summarized below, provide the background on our attempt to provide the CCPR with the requested aldicarb studies.

On October 24, 2018 AgLogic Chemical LLC was advised by Mr. Ian Reichstein that aldicarb was reinstated as a supported compound awaiting periodic review and would be placed as a confirmed listing for the 2020 Schedule.

We notified the CCPR that AgLogic is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US Environmental Protection Agency (EPA) by aldicarb's previous registrant, Bayer CropScience. We are not allowed to have copies of the actual studies that support registration and, therefore, despite our best intentions, we are not able to submit these studies to the JMPR for review.

We suggested that the since the EPA already has the supporting studies, the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR or, alternatively, the EPA could provide the required studies to the JMPR for review by someone not from the EPA.

On May 22, 2019 AgLogic Chemical was notified by Mr. Soren Madsen that the aldicarb studies should be submitted to the JMPR for review in order to avoid possible (or perceived) conflicts of interest. We were told that the JMPR secretariat seeks to assign monographers and reviewers that have not been directly involved in recent national evaluations of the assigned compound.

We immediately contacted the EPA and asked if they could submit the aldicarb studies directly to the JMPR and EPA said that it was most appropriate to work through the Freedom of Information Act (FOIA). That determination was made based upon the requirements set forth under Section 10(g) of FIFRA, which, in part, restricts the availability of how

studies/data submitted to the EPA can be released to a specific requestor. At this point the EPA Office of General Counsel contacted Bayer CropScience to get their consent to release the aldicarb studies to the JMPR.

On July 29, 2019 AgLogic Chemical was notified that Bayer decided not to consent to the EPA's direct release of aldicarb toxicology and residue studies to the JMPR. However, the EPA said they would consider if it was possible for them to provide the studies directly to the CCPR without agreement from Bayer.

On September 27, 2019 the EPA stated *"To pursue a definitive decision, CCPR would need to submit a FOIA request, identify the specific studies being requested, and identify all individuals who would have access to the requested studies. EPA would require signed Affirmations of Non-multinational Status from each of those individuals as one of the initial steps after receiving the request. I don't know if EPA would be able to make a final determination on disclosure by December 1, 2019."*

While the studies requested are in the public domain, the only way that the aldicarb studies can be provided to the CCPR is through Freedom of Information requests that are submitted to the EPA by the assigned CCPR reviewers. If this procedure is acceptable Ag Logic Chemical will identify the specific aldicarb studies that should be requested under FOIA. We will include the complete study title and MRID number so that EPA will not have any problem locating the correct studies. We will provide the list of studies to the CCPR so they can submit the FOIA requests.

As it is unlikely that this process can be completed by December 1, 2019, we propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the EPA to submit the studies to the CCPR.

Please let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800